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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,187	09/21/2001	Karen E. Sandman	NEB -164-PUS	4950

28986 7590 12/21/2005

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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,187	SANDMAN ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-58* is/are pending in the application.

4a) Of the above claim(s) *46,47 and 49-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-48, 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

NOTE the change of examiner in this application.

1. The amendment and the response filed on 8/19/05 has been fully considered and entered into the application.

Status of Claims

2. The previous amendments to the claims filed on 7/9/04, canceled claims 22-39 and added new claims 40-58. This amendment was improper and non-complaint because the amendment cancels claims 22-39. However, the instant application does not have claims 38-39 ever pending or filed in this application. The amendment filed on 3/26/04 has canceled claims 3-20 and added new claims 21-37. Applicants are requested to take appropriate action to correct the errors in claims and claim numbering.

3. Claims 40-58 are currently pending.

4. Claims 46-47 and 49-58 are withdrawn from consideration as being directed to a nonelected invention.

5. Claims 40-45 and 48 are under consideration to the extent they read on the elected invention.

Election/Restrictions

6. Applicant's election of group I, Claims 40-45, 48 in the reply filed on 3/28/04 (confirmed in the previous office action) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

7. Claims 46-47 and 49-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

8. This application contains claims 46-47, 49-58 drawn to an invention nonelected with traverse in Paper filed on 3/28/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

11. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 371 and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicants amendments filed on 8/19/05 has overcome the new matter rejection of record. However, the priority filing date of the instant invention is considered as the filing date of the PCT/US00/13292, filing date of 5/12/00.

The terms '**amplifiable genetic particle**'; '**a polysome, a virus, a cell or a spore**' are not sufficiently disclosed in the provisional application 60/134,286 filed on 5/14/99.

Accordingly, effective filing date of the invention is determined as the filing date of the PCT application for purposes of prior art.

Withdrawn Claim Rejections

12. The rejection of claims 40-45, 48 under 112, second paragraph, have been withdrawn in view of the amendments filed on 8/19/05.

13. The new matter rejection of claims40-45 and 48 set forth in the previous office action has been withdrawn in view of the amendments to the claims.

Maintained Claim Rejections

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. The lack of written description rejection of claims claims40-45 and 48 set forth in the previous office action for the reasons have been maintained for the reasons of record.

16. The rejection of claims 40-45 and 48 under 35 U.S.C. 102(a,b) as being anticipated by Sandman et al., JACS Vol. 122, pages 960-961 (Feb. 2000) is maintained for the reasons of records set forth in the previous office action mailed on 2/17/05.

17. The rejection of claims 40-45 and 48 are rejected under 35 U.S.C. 102(a,b) as being anticipated by Sandman et al., Nucleic Acid Res. Vol. 28(3) (2000) pages 755-761 is maintained for the reasons of records set forth in the previous office action mailed on 2/17/05.

18. The rejection of claims 40-45 and 48 are rejected under 35 U.S.C. 102(a,b,e) as being anticipated, or alternatively obvious under 35 U.S.C. 103, over Larsen et al. US Pat. No. 5,272,078 (12/93) alone, or if necessary further in view of Holliger et al. Structure, Vol. 5(2)

(1997) pages 265-275 as evidence of inherency, is maintained for the reasons of records set forth in the previous office action mailed on 2/17/05.

Response to Arguments

19. Claims 40-45 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (Lack of Written Description).

It is first noted that written description is legally distinct from enablement: "Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co*

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)

(bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)]. As further stated by the Lilly court, the name if it does no more than distinguish the claimed genus from all others by function does not satisfy the written description requirement because it does not define any structural features commonly possessed by members of the genus that distinguish them from the others" See 43 USPQ2d at 1406.

The presently claimed invention broadly encompasses fusion proteins comprising:

a. a "selenocysteine containing peptide" covalently linked to

b. a "surface protein" positioned on an "amplifiable particle".

Accordingly, the peptide portion of the fusion protein has no fixed amino acid structure, length, conformation, function or source, but merely requires the presence of one (or more) selenocysteines.

Additionally, "surface protein" is not limited by amino acid structure, length, conformation, function or source.

Finally, the term "amplifiable particle" is not defined in the specification but merely enumerated to encompass phage, polysome, virus, cell or spore.

In support thereof the specification provides nucleic acid constructs for the fusion of a selenocysteine peptide to the M13 phage coat protein (e.g. g3p), which is not representative of:

a. all amplifiable genetic particles or even polysome, virus, cell or spore claimed;

b. any "surface protein" from whatever source (e.g. phage or non-phage); and

c. the requisite genetic constructs for a. and b.

Accordingly, applicant has failed to demonstrate possession of the open-ended genus of possible fusion protein and underlying genetic encoding constructs. In this regard, applicant is further referred to *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997); "Guidelines for Examination of Patent Applications Under the 35 USC 112, first paragraph, 'Written Description' Requirement" published in 1242 OG 168-178 (January 30, 2001); and Univ. Of Rochester v G. D. Searle and Co. 249 F. Supp. 2d 216 (W.D.N.Y. 2003) affirmed by the CAFC on February 13, 2004 (03-1304) publication pending.

20. Applicant's arguments filed 8/19/05, regarding the 'lack of written description rejection', have been fully considered but they are not persuasive.

Applicants argue that the new amendments to the claims would overcome the rejections of record. Applicants arguments are not persuasive, since the

Applicants argue that the definition of 'amplifiable genetic particle as a phage, cell, spore

or virus' is accepted by those of ordinary skill in the art, and refers to US Patent 5,223,409.

Applicants arguments have been considered and are not persuasive, since the use of cell, spore or polysome as amplifiable genetic particle is not supported in the specification. Applicants seem to be arguing the enablement of 'cell, or polysome or spore', however the instant rejection is set forth as lack of written description. The specification disclosure uses phage display vectors to display selenocysteine-containing peptide. The provisional application disclosure is based solely the use of the phage display vectors, and no disclosure of the use of spore, polysome, cell or virus as amplifiable genetic vector.

Applicants reference to US Patent 5,223,409 as a support for the disclosure of the 'cell, spore or polysome' as amplifiable genetic particle.' Since the rejection is based on written description, and the instant specification has not disclosed the selenocysteine containing peptides displayed on 'cell, spore or polysome'. Further the reference to Jockson et al (2005), Wernerus (2004) as support for the instant claimed invention is not persuasive since these reference are after the filing date of the claimed invention. Kieke et al teaches the use of Yeast cells as amplifiable genetic particles, does not support the instant claim.

Applicants further argue that 'the ruling of the University of California V. Eli Lilly' is not applicable. This is not persuasive, since the instant claimed invention lacks a core structure. Applicants seem to be arguing that 'selenocysteine' is the core structure of the peptide, which is not convincing. Because in the claimed 'selenocysteine-containing peptide' the number or the position of the selenocystiens in the peptide is open. Thus the argument that the presence of the selenocysteine in a peptide is not sufficient for written description.

And applicants arguments that it is well known in the art that 'an important function of a peptide fused to the surface of a protein on an amplifiable genetic particle for purpose of screening libraries of peptides.' Applicants arguments regarding the screening assay, or the describing the peptide structures of each peptide in the library. Applicants arguments are not persuasive, because the instant specification neither disclosed the core structure or the shared feature to all members of the library, nor the length of the peptides, nor the number of selenocysteines present in the peptide, nor the position of the selenoysteines in the peptides. Thus, for the reasons of record the rejection has been maintained.

21. Claims 40-45 and 48 are rejected under 35 U.S.C. 102(a,b) as being anticipated by Sandman et al., JACS Vol. 122, pages 960-961 (Feb. 2000) .

The presently claimed invention (e.g. claim 40) broadly encompasses fusion proteins comprising:

a. a "selenocysteine containing peptide" covalently linked to

b. a "surface protein" positioned on an "amplifiable particle".

The reference discloses that selenopeptides can be recombinantly expressed as N-terminal fusions (e.g. covalently linked) to M13 phage (e.g. "an amplifiable particle") coat protein III (e.g. surface protein with "native peptide bond" and "positioned on "the amplifiable particle") "at a predetermined, unique site" anticipating claims 40-43. Claims 44, 45 and 48 are drawn to "product-by-process" limitations, which is met by the reference product, which is within the presently claimed scope, regardless of means of manufacture. Alternatively, the reference appears to teach the process limitations e.g. the use of a TGA codon (encoding SeCis) "adjacent" to a SeCis insertion sequence (e.g. derived from a eubacteria, eukarya or archea). See entire document ; especially abstract ; figures and protocol.

22. Claims 40-45 and 48 are rejected under 35 U.S.C. 102(a,b) as being anticipated by Sandman et al., Nucleic Acid Res. Vol. 28(3) (2000) pages 755-761.

The presently claimed invention (e.g. claim 40) broadly encompasses fusion proteins comprising:

a. a "selenocysteine containing peptide" covalently linked to

b. a "surface protein" positioned on an "amplifiable particle".

The reference discloses that selenopeptides can be recombinantly expressed as N-terminal fusions (e.g. covalently linked) to M13 phage (e.g. "an amplifiable particle") coat protein III (e.g. surface protein with "native peptide bond" and "positioned on "the amplifiable particle") "at a predetermined, unique site" anticipating claims 40-43. Claims 44, 45 and 48 are drawn to "product-by-process" limitations, which is met by the reference product, which is within the presently claimed scope, regardless of means of manufacture. Alternatively, the reference appears to teach the process limitations e.g. the use of a TGA codon (encoding SeCis) "adjacent" to a SeCis insertion sequence (e.g. derived from a eubacteria, eukarya or archea). See entire document ; especially abstract ; figures and protocol.

23. Applicant's arguments filed on 8/19/05, regarding the art rejections over Sandman references have been fully considered but they are not persuasive.

Applicants argue that both the Sandman references (Sandman et al., JACS Vol. 122, pages 960-961 (Feb. 2000), and Sandman et al., Nucleic Acid Res. Vol. 28(3) (2000) pages 755-761) were published after the filing date of the provisional application from which the present application gains priority and therefore do not constitute prior art.

Applicants arguments are not persuasive, because as discussed in the 'priority' section supra, the instant invention gets the priority date of only the filing date of the PCT application that is 5/12/00. And both the Sandman references were well before the PCT filing date such the references are prior art under 35 USC. 102 (a). Thus, the rejections of record over Sandman et al have been maintained.

24. Claims 40-45 and 48 are rejected under 35 U.S.C. 102(a,b,e) as being anticipated, or alternatively obvious under 35 U.S.C. 103, over Larsen et al. US Pat. No. 5,272,078 (12/93) alone, or if necessary further in view of Holliger et al. Structure, Vol. 5(2) (1997) pages 265-275 as evidence of inherency.

The presently claimed invention (e.g. claim 40) broadly encompasses fusion proteins comprising:

a. a "selenocysteine containing peptide" covalently linked to

b. a "surface protein" positioned on an "amplifiable particle".

The reference discloses that selenopeptides (e.g. 5'deiodinase variant mutants) can be recombinantly expressed in M13 phage (e.g. "an amplifiable particle") thus anticipating or alternatively rendering obvious the production of such mutants using M13 phage. See col. 15-16. Hollinger (e.g. see abstract; page 266, left column; Figure 1)teach that M13 phage display the selenopeptides (e.g. library) fused to the N terminus of the M13 coat protein (e.g. gIII p) (e.g. surface protein with "native peptide bond" and "positioned on "the amplifiable particle") "at a predetermined, unique site" anticipating claims 40-43. Claims 44, 45 and 48 are drawn to "product-by-process" limitations, which are met by the Larsen reference product, which is within the presently claimed scope, regardless of means of manufacture. Alternatively, the Larsen reference appears to teach the process limitations e.g. the use of a TGA codon (encoding SeCis) "adjacent" to a SeCis insertion sequence (e.g. derived from a eubacteria, eukarya or archea). See entire document; especially abstract ; examples; figures and protocol (e.g. col. 9-14).

25. Applicant's arguments filed on 8/19/05, regarding the rejection of claims over Larson et al or in combination with Holliger et al have been fully considered but they are not persuasive.

Applicants argue that nowhere in Larson reference teaches the selenocyteine containing peptide is displayed on the surface of the M13 phage.

Applicant's arguments are not persuasive, since the reference tteaches the use of M13 phage to recombinantly express the selenopeptides, the reference clearly anticipates the claimed invention. It is well known in the art that the M13 phage display the fusion proteins (or recombinant proteins) of the coat protein and the protein or the peptide of interest together (fusion proteins) display on the surface of the phage particles. Thus, the reference anticipates the claimed invention.

Further Holliger teaches peptides fused to the N terminus of the M13 coat protein. Thus, Larson anticipates the claimed invention as evidenced by Holliger. Thus, for the reasons of record the rejections have been maintained.

Conclusion

26. No claims are allowed.

27. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

PADMASHRI PONNALURI
PRIMARY EXAMINER

15 December 2005